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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

WARE, TODD

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 12/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/810,939

Applicant(s)

CAPELLI-SCHELLPFEFFER,
MARY

Examiner

Todd D Ware

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 September 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-79 is/are pending in the application.
- 4a) Of the above claim(s) 12,13,15,38,39,52-56,62-66,75,76 and 79 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11,14,16-37,40-51,57-61,67-74,77 and 78 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Receipt of declaration filed 6-18-01, information disclosure statements filed 8-17-01 and 9-16-02 and election also filed 9-16-02 is acknowledged.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-11, 14, 16-37, 40-51 and 57-61, 67-74, 77-78, drawn to a method of improving the size and appearance of a healed wound with a cyclo-oxygenase/NF- κ B inhibitor and compositions and kits therefore, classified in class 514, subclass 886.
 - II. Claims 52-56, drawn to a method of improving the size and appearance of a healed wound with an anti-irritant compound, classified in class 424, subclass 443.
 - III. Claims 12-13, 15, 38-39, 62-66, 75-76, and 79, drawn a method of improving the size and appearance of a healed wound with a cyclo-oxygenase/NF- κ B inhibitor and an antipruritic/antiirritant compound.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not used together and have different modes

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of operation. The mechanism of the anti-irritant method does not appear to occur through inhibition of cyclo-oxygenase/NF- κ B.

3. Inventions I and III are related as mutually exclusive species in an intermediate-final product relationship. Distinctness is proven for claims in this relationship if the intermediate product is useful to make other than the final product (MPEP § 806.04(b), 3rd paragraph), and the species are patentably distinct (MPEP § 806.04(h)). In the instant case, the intermediate product is deemed to be useful as an anti acne formulation and the inventions are deemed patentably distinct since there is nothing on this record to show them to be obvious variants. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions anticipated by the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

4. Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not used together and have different modes of operation. The mechanism of the anti-irritant method does not appear to occur through inhibition of cyclo-oxygenase/NF- κ B.

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5. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.
6. During a telephone conversation with Anne Collins on 12-12-02 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-11, 14, 16-37, 40-51 and 57-61, 67-74, 77-78. Affirmation of this election must be made by applicant in replying to this Office action. Claims 12-13, 15, 38-39, 52-56, 62-66, 75-76, and 79 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.
7. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Specification

8. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.
9. The following title is suggested: Methods for improving size and appearance of a healed wound.

Claim Rejections - 35 USC § 112

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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11. Claims 67-68 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

12. Claim 67-68 provides for the use of a cyclooxygenase or NF-κB inhibitor, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections - 35 USC § 101

13. Claims 67-68 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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15. Claims 1-4, 8, 11, 27-30, 34, 37 and 67-68 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Sibley et al (DE 21 07 537; hereafter '537).

'537 discloses salicylic acid formulations for treatment of keloids caused by acne.

The formulations also disclose inclusion of substances that relieve skin irritation.

16. Claims 1-4, 8, 11, 27-30, 34, 37, and 67-68 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Singer (4,346,108; hereafter '108).

'108 discloses ibuprofen formulations for treatment of healed wound adhesions due to trauma.

Claim Rejections - 35 USC § 103

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

18. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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19. Claims 1-4, 7-8, 10-11, 27-30, 33-34, 36-37, 67-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sibley et al (DE 21 07 537; hereafter '537).

20. '537 discloses salicylic acid formulations for treatment of keloids caused by acne. Adjustment of the amount of active would have been obvious to one skilled in the art at the time of the invention with the motivation of increasing or decreasing the amount of effect based upon the scar being treated.

21. Claims 1-4, 7-8, 11, 27-30, 33-34, 37, and 67-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Singer (4,346,108; hereafter '108).

22. '108 discloses ibuprofen formulations for treatment of healed wound adhesions due to trauma. Adjustment of the amount of active would have been obvious to one skilled in the art at the time of the invention with the motivation of increasing or decreasing the amount of effect based upon the scar being treated

23. Claims 1-8, 10-14, 16-22, 25-34, 36-47, 50-51, 57-61, 67-74, and 77-78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sibley et al (DE 21 07 537; hereafter '537) in view of Lee (5,552,162; hereafter '162).

24. '537 is relied upon for all that it teaches as stated previously. '537 does not teach combination of the formulation with a thermal insulating material.

25. '162 teaches improvement of scar size and appearance with a thermal insulating material such as a hydrogel, combined with a medicament.

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26. Accordingly, it would have been obvious to one skilled in the art at the time of the invention to combine '537 and '162 with the motivation of providing a formulation having an additive scar reduction ability.

27. Claims 23-24 and 48-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sibley et al (DE 21 07 537; hereafter '537) in combination with Lee (5,552,162; hereafter '162) and further in combination with Allen (4,895,727; hereafter '727).

28. '537 and '162 are relied upon for all that they teach as stated previously. Neither reference teaches inclusion of a deodorant agent such as aluminum zirconium trichlorohydrate or zinc acetate.

29. '727 is relied upon for teaching that zinc acetate increases the penetration of salicylic acid.

30. Accordingly, it would have been obvious to one skilled in the art at the time of the invention to include zinc acetate in the combined formulation of '537 and '162 with the motivation of increasing the penetration of salicylic acid through the skin.

31. Claims 9 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sibley et al (DE 21 07 537; hereafter '537) in view of Boghosian et al (4,244,948; hereafter '948).

32. '537 is relied upon for all that it teaches as stated previously. '537 does not teach the acetylsalicylic esters of instant claims 9 and 35.

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33. '948 is relied upon for teaching that acetylsalicylic esters retain the anti-inflammatory properties of acetylsalicylic acid and that the acetylsalicylic esters penetrate the skin more readily with decreased irritation to the skin than acetylsalicylic acid.

34. Accordingly, it would have been obvious to one skilled in the art at the time of the invention to substitute acetylsalicylic esters with the motivation of providing a form having increased penetration to the skin with decreased irritation.

Conclusion

35. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Todd D Ware whose telephone number is (703) 305-1700. The examiner can normally be reached on M-F, 8:00 AM - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703)308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

tw
December 15, 2002


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